

David W. Scofield - 4140 <b>PETERS   SCOFIELD</b> <i>A Professional Corporation</i> 7430 Creek Road, Suite 303 Sandy, Utah 84093-6160 Telephone: (801) 322-2002 Ext. 102 Direct Dial: (801) 858-3402 Toll Free: (888) 296-3998 Facsimile: (801) 912-0320 Email: <a href="mailto:dws@psplawyers.com">dws@psplawyers.com</a>	<b>POMERANTZ LLP</b> Jeremy A. Lieberman <i>(Pro Hac Vice Pending)</i> J. Alexander Hood II <i>(Pro Hac Vice Pending)</i> 600 Third Avenue, 20th Floor New York, New York 10016 Telephone: (212) 661-1100 Facsimile: (212) 661-8665 Email: <a href="mailto:jalieberman@pomlaw.com">jalieberman@pomlaw.com</a> Email: <a href="mailto:ahood@pomlaw.com">ahood@pomlaw.com</a>	<b>BRONSTEIN, GEWIRTZ &amp; GROSSMAN, LLC</b> Peretz Bronstein <i>(Pro Hac Vice Pending)</i> 60 East 42nd Street, Suite 4600 New York, NY 10165 Telephone: (212) 697-6484 Facsimile: (212) 697-7296 Email: <a href="mailto:peretz@bgandg.com">peretz@bgandg.com</a>
---	---	--

**UNITED STATES DISTRICT COURT  
DISTRICT OF UTAH  
CENTRAL DIVISION**

FERNANDO HERNANDEZ, Individually  
and on Behalf of All Others Similarly  
Situating,

Plaintiff,

v.

CO-DIAGNOSTICS, INC., DWIGHT  
EGAN, JAMES NELSON, EUGENE  
DURENARD, EDWARD MURPHY,  
RICHARD SERBIN, REED BENSON,  
and BRENT SATTERFIELD,

Defendants.

**CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS**

**JURY TRIAL DEMANDED**

Civil No. 2:20-cv-00481-DAO

Honorable Daphne A. Oberg  
United States Magistrate Judge

Plaintiff Fernando Hernandez (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States

(“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Co-Diagnostics, Inc. (“Co-Diagnostics” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants who purchased or otherwise acquired Co-Diagnostics securities between February 25, 2020 and May 15, 2020, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. As the COVID-19 global pandemic began to spread to the U.S., government and public health officials on the state and federal levels moved quickly to establish strategies to prevent the disease from devastating the country. Universally, those government strategies were predicated on establishing effective systems for mass testing of the U.S. population for the COVID-19 virus.

3. Fast, accurate, and readily accessible testing for COVID-19 provides government officials with crucial health information and data needed to combat the pandemic. It allows them to assess, in real-time, outbreaks of the virus and to take appropriate policy actions, such as quarantining and social distancing measures intended to prevent further mass transmission. It also allows them to allocate and, if necessary, seek resources to ensure that our public and private health systems can appropriately provide care for COVID-19 patients who require medical intervention and treatment.

4. To be sure, the ingenuity and industriousness of American enterprise has been integral to the country's response to the COVID-19 pandemic. Health officials have worked closely with U.S. and international medical and pharmaceutical companies to develop COVID-19 tests, to seek potential therapeutics for the virus, and to ultimately obtain a vaccine. Additionally, many American companies have stepped up to this tremendous challenge, working with government counterparts to mitigate and hopefully end this pandemic.

5. There are, however, some companies and corporate executives who have sought to unfairly exploit this novel pandemic for their financial gain, including by, among other things, misleading the public about the efficacy of their products in combatting the pandemic. Defendant Co-Diagnostics is one of those companies.

6. As explained in greater detail below, Co-Diagnostics, its directors and officers—including PhD-level scientists who should know better—made continual, knowing and willful misstatements about their main product, a COVID-19 diagnostic test, to pump up the price of Co-Diagnostics' stock while the officers and directors exercised low priced options and dumped their stock into the market. Their fraudulent misstatements, and disregard for the basic scientific principles that make their falsity of their statements clear in retrospect, caused investors to lose millions of dollars.

7. Early in the COVID-19 pandemic, drug companies were racing to create an accurate diagnostic test for the virus that had quick response times. Co-Diagnostics seemingly won that race. Co-Diagnostics announced that it had received regulatory clearance to sell its tests in the European Community on February 24, 2020—the first company in the world to receive such clearance. Then, on April 6, 2020, the Company announced that it had received emergency use authorization for its tests from the U.S. Food and Drug Administration ("FDA").

8. Throughout this time and thereafter, Co-Diagnostic and its officers and directors, made unequivocal statements to the market that its COVID-19 tests were 100% accurate—a staggering claim that appeared to set Co-Diagnostics apart from other competitors developing COVID-19 tests. As was later revealed, however, this was not true: Co-Diagnostics’ COVID-19 tests are materially less than 100% accurate—a discrepancy that can have momentous adverse consequences if Co-Diagnostics’ tests are used on a widespread basis, as intended.<sup>1</sup> Nonetheless, Co-Diagnostics’ market-first test, together with its claims that its tests were perfectly accurate, allowed Co-Diagnostics to sign lucrative contracts with state governments in the U.S. and governments around the world.

9. As a result of this misrepresentation and the influx of taxpayer dollars to Co-Diagnostics, the Company’s stock soared—until it crashed. The crash came when Co-Diagnostics began acting evasively about its COVID-19 tests’ true accuracy and regulatory authorities contradicted claims made by Co-Diagnostics about the accuracy of diagnostic tests.

10. Prior to the release of the news undermining Co-Diagnostics’ false claims of 100% accuracy, Co-Diagnostics’ stock enjoyed an all-time high stock price of \$29.72 per share and a market capitalization of over \$800 million. This was quite an accomplishment for a company that was at risk of being delisted from the exchange on New Year’s Day, 2020, when it was trading at \$0.91 per share and was worth less than \$25 million. Just a year ago, Co-Diagnostics was in danger of being delisted from NASDAQ on July 2, 2019, because it was consistently trading under a

---

<sup>1</sup> As stated herein, diagnostics tests that are even slightly less than 100% accurate in clinical testing can have extraordinary public health consequences when it comes to practical testing accuracy in a field setting. For example, if a diagnostics test has a 98% “specificity” and “sensitivity” rate (two metrics that factor into a test’s accuracy), the practical effect is that 1 in 3 tests will return false positive results for COVID-19. For this reason, it is critical that market leaders in this area have nearly perfect accuracy metrics in clinical settings.

dollar—now it was trading at thirty times that. Co-Diagnostics officers and directors were poised to make a fortune on the inflated stock price.

11. On May 14, 2020, Co-Diagnostics was set to announce its first quarter earnings after markets closed. Before the markets closed and before the earnings call, however, news outlets reported that Co-Diagnostics was reticent to participate in U.S.-based testing to verify its accuracy claims.

12. As public reports casting doubt on Co-Diagnostics' claims of 100% accuracy began to circulate, the stock rapidly declined. After negative information about Co-Diagnostics' tests began to be reported, the stock went from its high of \$29.52 per share, down to \$20.00 per share, and hit an intra-day low of \$18.35 per share before closing at \$22.13 per share. The losses on May 14, 2020, were so sudden that the stock stopped trading at one or two periods during the day, and its losses may have been higher but for NASDAQ's intervention.

13. After markets closed and with this information in hand, Co-Diagnostics issued an earnings report for the first quarter of 2020 and held a call that commented on the Company's future prospects. On the call, Chief Executive Officer ("CEO") Dwight Egan ("Egan") offered a glowing report explaining that the Company had sold 6 million tests, and had already purchased components to manufacture an additional 20 million tests that were already ordered by customers.

14. On the call, neither Egan nor its Chief Financial Officer ("CFO"), Reed Benson ("Benson"), made mention of the public statements made by third parties relating to the tests' accuracy. Notably, Chief Science Officer ("CSO"), and inventor of Co-Diagnostics' technology, Brent Satterfield ("Satterfield"), Ph. D., was absent from the call and did not address the allegations after boasting to the market about Co-Diagnostics' COVID-19 testing accuracy in press releases in the weeks leading up to the Company's earnings announcement.

15. That evening, in response to other drug companies' widely-reported test accuracy struggles, financial news services began reporting that the FDA announced publicly that no COVID-19 test is 100% accurate. This announcement by the FDA undermined Co-Diagnostics' claims about its tests' perfect accuracy.

16. When markets opened on May 15, 2020, the stock slid to a low of \$15.80 per share. The stock never rebounded, and today trades at a significantly reduced volume and stock price, with expectations that the stock will trend lower because of the Company's product not being what it was promised to be, public skepticism, and the realization by investors that Co-Diagnostics was a flash-in-the-pan company that achieved astronomical gains by deceiving the public while it was wrestling with an unprecedented global pandemic.

17. During this time, and with a cloud of doubt hanging over the Company's claims of accuracy, Co-Diagnostics' directors and officers have been rapidly exercising stock options for pennies per share and immediately selling their shares into the market reaping millions of dollars from the fraud-inflated price of the stock. The Company's officers and directors, knowing the truth of the Company's products and its future prospects, are taking their profits at cost to the public markets before the Company inevitably becomes a penny stock once more. The investing public at large does not have the luxury of purchasing its shares at pennies on the dollar. Investors who believed Co-Diagnostics' claims of 100% accuracy have lost hundreds of millions of dollars as a result of Co-Diagnostics' blatantly fraudulent statements to the investing public.

18. This class action, therefore, seeks to hold Co-Diagnostics and its executives accountable for their misrepresentations on behalf of defrauded investors.

### **JURISDICTION AND VENUE**

19. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

21. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Co-Diagnostics is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

22. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

### **PARTIES**

23. Plaintiff, as set forth in the attached Certification, acquired Co-Diagnostics securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

24. Defendant Co-Diagnostics, Inc. is a Utah Corporation with offices in Salt Lake City, Utah.

25. Defendants Dwight Egan, James Nelson, Eugene Durenard, Edward Murphy, Richard Serbin, Reed Benson, and Brent Satterfield are directors and/or officers of Co-Diagnostics. Upon information and belief, each individual defendant resides and conducts business in the State of Utah.

26. The Defendants named above, other than Co-Diagnostics, are referred to herein as the “Individual Defendants.” The Individual Defendants possessed the power and authority to control the contents of Co-Diagnostics’ SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Co-Diagnostics’ SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Co-Diagnostics, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

27. Co-Diagnostics and the Individual Defendants are sometimes collectively, in whole or in part, referred to herein as the “Defendants.”

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

28. Co-Diagnostics was formed on April 18, 2013, as a Utah corporation. Upon information and belief, the Company was formed to monetize the DNA-testing technology developed by Biomedical Engineering Ph.D. Defendant Satterfield

29. Defendant Egan, Co-Diagnostics’ current CEO, joined the Company as an officer and director in April 2013.

30. Defendant Benson has served as the company’s CFO, board secretary, and as a director of Co-Diagnostics since 2014.

31. After several years of operating as a “start-up” in the private sector, Co-Diagnostics filed an SEC Form S-1 Registration Statement on April 28, 2017, with an attached prospectus.



32. The prospectus described that the Company owned proprietary technology that enabled it to do DNA testing for diagnostic purposes.

33. For example, the prospectus stated that, as of 2017, Co-Diagnostics' primary source of revenue was from selling diagnostics tests for Zika Virus, Tuberculosis, Hepatitis B, Hepatitis C, Malaria, Dengue Fever, and HIV. Its customers were primarily located in the Caribbean, India, North America, South America, and Central America.

34. The Company forecasted that it would be authorized to sell Tuberculosis, Hepatitis B, and Hepatitis C tests in the European Union in 2018 and 2019.

35. The prospectus admits that beyond 2019, the Company did not have a plan for further research and development or any target diseases that it was aiming to create diagnostic tests for, but anticipated selling tests "based on need and regulatory barriers" in the U.S.

36. The stock first listed on the NASDAQ exchange on July 12, 2017, and opened at \$6.00 per share. The stock slowly slid down in price to become a "penny stock" trading at less than \$1.00 per share for extended periods. The stock closed on December 31, 2019, at \$0.89 per share.

37. Co-Diagnostics was in danger of being delisted from the NASDAQ, which requires that companies not trade below \$1.00 per share to continue being listed on the exchange.

38. As is now common knowledge, in late 2019, a new virus began to spread rapidly through the population in Wuhan, China. That virus, which has become known as COVID-19, has ravaged the world's economies and healthcare systems, and has resulted in millions of infections and hundreds of thousands of deaths. COVID-19 is a virus, and it can be detected by DNA-based testing. Because Co-Diagnostics' expertise is DNA-based testing, the world's need for accurate

COVID-19 testing—to help control the spread of the virus—presented a unique opportunity to Co-Diagnostics to use its technology and expertise to earn money.

39. According to Co-Diagnostics, it began developing COVID-19 tests rapidly using a technology called CoPrimer, which was developed and patented by Defendant Satterfield before the outbreak. Based on public reports, Co-Diagnostics used the CoPrimer technology to develop a COVID-19 diagnostics test within one week.

40. CoPrimer allegedly worked so well that Co-Diagnostics, despite its relatively small size, became the first company in the world to obtain the prestigious CE marking for its COVID-19 tests. The CE certification mark indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area.

41. Co-Diagnostics announced on February 24, 2020, that it had received regulatory approval to sell in the European Community. It was the first U.S. company to receive approval for the export to Europe of COVID-19 test kits.

42. Co-Diagnostics' stock began to rise on this news. The stock traded at over \$15.00 per share at the end of February 2020, and at over \$17.00 per share in early March.

43. On April 6, 2020, Co-Diagnostics became the first company to receive approval from the FDA for its COVID-19 tests under an Emergency Use Authorization, which permitted Co-Diagnostics' tests to be used by certified clinical laboratories in the U.S. for the diagnosis of COVID-19.

44. The stock, which in the weeks after the CE announcement had settled to \$8.00 per share, began to climb again.

45. Co-Diagnostics rushed its product to market because it had many larger competitors who were also hurrying to get an accurate diagnostic test to market.

**Materially False and Misleading Statements Issued During the Class Period**

46. After Co-Diagnostics obtained its certifications, it began selling millions of dollars' worth of COVID-19 tests to fifty countries and more than twelve states in the U.S. The stock continued to climb.

47. During this time Co-Diagnostics was able to obtain lucrative contracts to provide testing to states and foreign countries. For example, Co-Diagnostics was going to provide the majority of the tests for a \$5 million contract with the state of Utah that ran from March 31, 2020 through May 30, 2020. Co-Diagnostics was also to provide tests for a contract with Iowa totaling \$26 million for approximately 540,000 testing kits.

48. Not all news was good, however. On April 30, 2020, *The Salt Lake Tribune* ("*Tribune*") published an article entitled "'This is a Potential Public Health Disaster': COVID-19 results from TestUtah.com are raising questions." The article questioned the accuracy of Co-Diagnostics' tests being used at sites run by TestUtah.com.

49. Defendant Satterfield was quoted in the article, reassuring the public that the alleged inaccuracies were because of "population differences".

50. In response to the *Tribune*'s questions, Defendant Satterfield reassured the market that Co-Diagnostics' tests were between 99.52% and 100% accurate in unspecified FDA and European studies. Satterfield also stated that the Company had received no complaints from anyone Co-Diagnostics supplied tests to in fifty countries.

51. On May 1, 2020, to allay public health and investor concerns, Co-Diagnostics issued a press release titled: "Co-Diagnostics, Inc. Releases COVID-19 Test Performance Data: Consistently Demonstrates 100% Sensitivity and 100% Specificity Across Independent Evaluations". The press release unequivocally stated that Co-Diagnostics' COVID-19 tests were 100% accurate based on data gathered from across the world:

Co-Diagnostics, Inc. (**Nasdaq:CODX**) (the Company), a molecular diagnostics company with a unique, patented platform for the development of diagnostic tests, today released COVID-19 test performance data demonstrating 100% sensitivity and 100% specificity, the metrics used to determine accuracy in molecular diagnostics testing.

The data being released comes from independent evaluations of the performance of the Company's COVID-19 test in the field. These evaluations were conducted in Mexico by the Mexican Department of Epidemiology ("InDRE"), India, and elsewhere in the US and abroad. Each study concluded 100% concordance for both specificity and sensitivity.

52. In the press release, Defendant Satterfield did not mention that the tests might be less than 100% accurate, abandoning his recognition that the tests were between 99.52% and 100% accurate. Instead, Satterfield insisted that Co-Diagnostics' tests were 100% accurate based on the experimental data:

In remarking on the test's favorable limit of detection (LOD) results in the evaluations, Brent Satterfield, PhD said, "In diagnostics, the limit of detection or LOD is a single metric that helps inform the key metrics of sensitivity and specificity but is not relevant as a stand-alone data point. Other metrics that are important are availability, ease of use and throughput. In countries where we have been evaluated against other tests, ***we have consistently and repeatedly achieved 100% clinical sensitivity and specificity and you can't do better than that.***"

(Emphasis added).

53. While in most situations, 99.5% accuracy and 100% accuracy are functionally equivalent, in diagnostic testing of diseases with a low population saturation, the difference can dramatically affect whether a test has any value to public health officials.

54. For example, in Utah, COVID-19 testing has fairly consistently resulted in only 5% of apparently-symptomatic test subjects testing positive for COVID-19. In other words, for every 1,000 tests, only about fifty people test positive. However, even if Co-Diagnostics' tests were 99.5% accurate—and it appears they are much less accurate than that—as described in greater detail below, there would be five people who did not have the test but who tested positive. In other

words, one in ten people who tested positive would not have the disease. At only slightly lower accuracy rates, the test becomes essentially worthless for public health testing and tracing.

55. In practice, Co-Diagnostics' results seemed to be even worse than these result rates would suggest. For example, the April 30th *Tribune* article reported that Co-Diagnostics' tests being used by TestUtah.com resulted in only a 1% to 2% positive test rate even in symptomatic patients, suggesting that Co-Diagnostics' tests were only accurately reporting half of the COVID-19 infections, suggesting an accuracy rate even worse than the 99.5% that Co-Diagnostics initially claimed and infinitely worse than the 100% accuracy rate Co-Diagnostics began to tout in early May 2020.

56. The market, however, accepted Co-Diagnostics' false claims of 100% accuracy, resulting in a boon to the Company's share price. For example, the following publications repeated Co-Diagnostics' claims, amplifying their effect on the market:

- “**Co-Diagnostics (CODX)** said Friday its coronavirus test has proven 100% accurate in field testing — leading CODX stock to rocket.” —Allison Gatlin, *Investor's Business Daily*, “Coronavirus Test Maker Soars As Its Diagnostic Proves 100% Accurate.”
- “Co-Diagnostics says coronavirus test shows spotless sensitivity data in independent evaluations” —*Proactiveinvestors.com*
- “Co-Diagnostics Is a Smart Way to Play Coronavirus Testing: The company's tests are reportedly 100% accurate in at least three countries” — Louis Navellier, *Investorplace.com*

57. Co-Diagnostics did not release any clarifying statement about the accuracy of its test and has not addressed the allegations in public filings or press releases.

58. Co-Diagnostics' stock continued to rise in May 2020, as investors anticipated an earnings announcement and financial report for the first quarter of 2020 on May 14, 2020, after markets closed.

59. Co-Diagnostics' plan to repress negative reports about its tests seemed to work. On May 14, 2020, the stock reached an all-time high of \$29.72 per share, an extraordinary climb from its \$0.89 per share year-end 2019 price.

60. However, around that same time, Co-Diagnostics' claims of test accuracy became unsustainable.

### **The Truth Begins to Emerge**

61. In the late morning and early afternoon of May 14, 2020, third parties revealed startling information about Co-Diagnostics' allegedly 100% accurate test.

62. The *Tribune* reported that TestUtah.com, which used tests developed by Co-Diagnostics, "declined to join other major Utah labs in a joint experiment to confirm one another's quality." Moreover, the *Tribune* revealed that TestUtah's tests (by Co-Diagnostics) "have a higher 'limit of detection' — that is, they require more of the virus to trigger a positive result — than most other coronavirus tests approved for sale in the U.S., according to an analysis by the life sciences publication BioCentury." This meant that Co-Diagnostics' tests were likely to have a much higher false negative reporting rate, meaning that potentially thousands of infected people were inaccurately told that they did not have the disease, an observation that was consistent with earlier concerns about TestUtah's lower rate of positive test results.

63. The *Tribune* article also expressed concern relating to TestNebraska.com and TestIowa.com testing services that also used Co-Diagnostics' tests.

64. Also on May 14, 2020, Iowa Governor Kim Reynolds issued a public statement, stating, "I'm pleased to announce that the State Hygienic Lab completed the Test Iowa validation process yesterday, achieving high ratings of 95 percent accuracy for determining positives and 99.7 percent accuracy for determining negatives." These results did not comport with statements previously made by Co-Diagnostics on May 1, 2020.

65. In fact, Defendant Satterfield himself has recently confessed that the lower positive rates for Co-Diagnostics' tests "has certainly got all of us scratching our heads a bit," and that the tests will correctly identify 95% of true positive results—a massive discrepancy from Co-Diagnostics' representations of 100% accuracy given that the tests are intended to be administered among hundreds of thousands or even millions of people.

66. Based on the release of third-party information casting serious doubt as to Co-Diagnostics' bold claims of 100% accuracy, the stock price began to fall, closing the day at \$22.13 per share on May 14, 2020, after hitting an intra-day low of \$18.35 per share, a greater than 38% decrease in price within hours.

67. At that point, Co-Diagnostics could have, but did not, revise its claims of 100% test accuracy, given that Co-Diagnostics released earnings and first quarter 2020 financials to the public after-hours and had a scheduled investor call for the same evening.

68. Co-Diagnostics reported that it achieved record sales and that the start-up had finally, after nearly seven years, reached profitability. However, it did not address the testing accuracy or sensitivity allegations or correct Defendant Satterfield's prior statements about tests being 100% accurate.

69. Rather, the call was described by *The Gazette*, a Cedar Rapids, Iowa publication covering TestIowa.com, as sounding "more like Thanksgiving with drunk uncles — dogs were barking, people were swearing, and someone was moaning." *The Gazette* also noted that "[n]one of Co-Diagnostics or Nomi Health's news releases about the Logix Smart tests have revealed how many tests have been sold, for how much, and so far all three testing initiatives in Iowa, Nebraska and Utah have been secretive about the tests and the results."

70. That same day, the FDA issued a press release about testing accuracy. Another, much larger drug company had created a diagnostic test for COVID-19 that was under increasing public scrutiny for apparent inaccuracy. The FDA announced to the public that “[t]he FDA looks at a variety of sources to identify and understand potential patterns or significant issues with the use of the Abbott test. *No diagnostic test will be 100% accurate* due to performance characteristics, specimen handling, or user error, which is why it is important to study patterns and identify the cause of suspected false results so any significant issues can be addressed quickly.” (Emphasis added).

71. Based on the multiple third-party sources revealing serious problems that were known, or should have been known, in advance of May 14, 2020, the stock price further fell to close at \$17.07 per share on May 15, 2020, or a decrease of 22.86% from the prior day’s closing price.

72. By May 20, 2020, a statistician, Zhiyuan Sun, wrote an article specifically about Co-Diagnostics’ allegedly 100% accurate COVID-19 test. Sun explained:

In May, Co-Diagnostics announced its COVID-19 in vitro test had been found to have 100% accuracy, 100% specificity (likelihood of preventing a false-negative error), and 100% sensitivity (likelihood of preventing a false-positive error), as per independent verification in laboratories across the world

\* \* \*

### **The devil is in the details**

To start off, Co-Diagnostics came to the conclusion that its test was 100% effective on all three diagnostic dimensions (specificity, accuracy, and sensitivity) based on studies with small sample sizes. For example, laboratory testing of the Logix test kit conducted in Australia involved about 100 COVID-19-positive patients and 100 COVID-19-negative patients. With a sample size that small, a low error rate, say 1% to 2%, could be really hard to detect. In fact, the study itself explicitly stated that the test could in fact be between 96% to 98% effective, rather than 100%.



In addition, the testing environment is by no means indicative of the actual prevalence of COVID-19 in the population at this point in the pandemic. Among the test samples, 50% contained SARS-CoV-2, and obviously, at this point, nowhere near half the people in the world have been exposed to the coronavirus. "But wait a minute!" the intelligent reader might say. "Nothing in the world is perfect, so who cares if a test's results are off by 1% or 3%? Effectiveness of 97% is still nothing short of an A-plus. You're just being a devil's advocate, Zhiyuan!" Unfortunately, this is one of the cases where it is critical to pay attention to the devil in the details. In fact, a 1% or 3% error rate can render a *in vitro* test almost useless. Here's why.

Let us assume, for the sake of argument, the true sensitivity of Logix is 98%, and its true specificity is also 98%. In other words, the probability of the test delivering a false positive is 2%, and the probability of the test returning a false negative is also 2%. Both of these values are directly stated as being probable in studies citing Logix's range of effectiveness, and they are valid assumptions given that the test has not been fully vetted by the FDA or other regulators. It is also common knowledge that because there are not enough viral tests for the COVID-19, the number of people who have the virus is likely to be significantly higher than official figures. For example, it is estimated that up to 4.1% of the residents of Los Angeles County have COVID-19 antibodies. Let's use that 4.1% figure in our calculations as a measure of prevalence of COVID-19 (a lower prevalence would hurt the test even more). Assuming 1 million people are given the Logix test, 41,000 should test positive for an ongoing SARS-CoV-2 infection. However, if the test provides a false negative 2% of the time, only 98% of those 41,000 -- 40,180 -- would show up as positives.

On the other hand, out of the 959,000 people who were actually negative for the virus, a 2% error rate would yield 19,180 cases of false positives -- individuals who don't have the disease despite the test saying they do. All told, that makes 59,360 people getting positive results, but only 40,180 of them would actually be positive. That yields a predictive value of 67.7%.

In other words, if the Logix test only works as well as it does in this scenario -- and it's right 98% of the time -- there's still a **1-in-3** chance that the test will indicate you have COVID-19 even though you don't! As one can see, a 32.3% false-positive error rate isn't very good at all. This problem gets worse if we assume the same prevalence, but lower Logix's potential sensitivity and specificity estimates to 95% for both. In this scenario, the probability of getting a false positive increases to 55.2%! While the results are surprising, they nonetheless use the basics of conditional probability; here is a calculator in case you want to try it out for yourself. Furthermore, a recent New York University study on COVID-19 *in vitro* tests developed by **Abbott Laboratories** (NYSE:ABT) found them to be widely inaccurate and unacceptable for use in patients. Keep in mind, those tests were also promoted as having 100% sensitivity and 99.9% specificity in earlier

investigations. Unfortunately, this just serves to highlight how difficult it is to develop an accurate test for diseases with a low rate of prevalence like COVID-19.

73. Co-Diagnostics knew that even a highly accurate test—such as 96%, 98%, or even 99%—was not the same, and not remotely as valuable, as a 100% accurate test. That is because having a 100% accurate test would have significantly distinguished Co-Diagnostics from other, larger, more reputable competitors introducing COVID-19 tests into the marketplace. Additionally, the widespread administration of a COVID-19 test that is even minimally inaccurate can have highly adverse public health consequences. Co-Diagnostics knew this, and so it intentionally issued statements to the public to fend off truthful analysis and scientific skepticism about its supposed miracle test.

#### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

74. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Co-Diagnostics securities during the Class Period (the “Class”); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

75. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Co-Diagnostics securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. For example, on the last two days of the Class Period alone, almost 75 million shares of Co-Diagnostics were bought and sold, meaning that each issued

and outstanding share of stock changed hands an average of three times on those days alone. Record owners and other members of the Class may be identified from records maintained by Co-Diagnostics or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

76. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

77. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

78. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Co-Diagnostics;
- whether the Individual Defendants caused Co-Diagnostics to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Co-Diagnostics securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

79. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

80. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Co-Diagnostics securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Co-Diagnostics securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

81. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

82. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

**COUNT I**

**(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder  
Against All Defendants)**

83. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

84. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

85. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Co-Diagnostics securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Co-Diagnostics securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

86. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to

influence the market for Co-Diagnostics securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Co-Diagnostics' finances and business prospects.

87. By virtue of their positions at Co-Diagnostics, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

88. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Co-Diagnostics, the Individual Defendants had knowledge of the details of Co-Diagnostics' internal affairs.

89. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Co-Diagnostics. As officers and/or directors of a publicly held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Co-Diagnostics' businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public

statements, the market price of Co-Diagnostics securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Co-Diagnostics' business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Co-Diagnostics securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

90. During the Class Period, Co-Diagnostics securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Co-Diagnostics securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Co-Diagnostics securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Co-Diagnostics securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

91. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

92. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases,

acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

## **COUNT II**

### **(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)**

93. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

94. During the Class Period, the Individual Defendants participated in the operation and management of Co-Diagnostics, and conducted and participated, directly and indirectly, in the conduct of Co-Diagnostics' business affairs. Because of their senior positions, they knew the adverse non-public information about Co-Diagnostics' misstatement of income and expenses and false financial statements.

95. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Co-Diagnostics' financial condition and results of operations, and to correct promptly any public statements issued by Co-Diagnostics which had become materially false or misleading.

96. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Co-Diagnostics disseminated in the marketplace during the Class Period concerning Co-Diagnostics' results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Co-Diagnostics to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Co-Diagnostics within the meaning of Section 20(a) of the Exchange Act. In this capacity, they



participated in the unlawful conduct alleged which artificially inflated the market price of Co-Diagnostics securities.

97. Each of the Individual Defendants, therefore, acted as a controlling person of Co-Diagnostics. By reason of their senior management positions and/or being directors of Co-Diagnostics, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Co-Diagnostics to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Co-Diagnostics and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

98. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Co-Diagnostics.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action and certifying Plaintiff as the Class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

#### **JURY TRIAL DEMAND**

Plaintiff hereby demands a trial by jury.

DATED: July 2, 2020

Respectfully submitted,

**PETERS | SCOFIELD**  
*A Professional Corporation*

/s/ David W. Scofield

David W. Scofield

**POMERANTZ LLP**

Jeremy A. Lieberman  
(*Pro Hac Vice* Pending)  
J. Alexander Hood II  
(*Pro Hac Vice* Pending)  
600 Third Avenue, 20<sup>th</sup> Floor  
New York, New York 10016  
Telephone: (212) 661-1100  
Facsimile: (212) 661-8665  
Email: jalieberman@pomlaw.com  
Email: ahood@pomlaw.com

**BRONSTEIN, GEWIRTZ &  
GROSSMAN, LLC**

Peretz Bronstein  
(*Pro Hac Vice* Pending)  
60 East 42nd Street, Suite 4600  
New York, NY 10165  
Telephone: (212) 697-6484  
Facsimile: (212) 697-7296  
Email: peretz@bgandg.com

*Attorneys for Plaintiff*